

AMENDMENTS TO THE CLAIMS

Claims 1-66 (Canceled)

67. (Currently amended) A method for determining whether a biomolecule inhibits growth of cells *in vivo*, comprising:

- a) introducing a cell having an exogenous regulable gene encoding a biomolecule into one or more test animals and into one or more control animals, wherein the biomolecule binds a protein target component of the cells;
- b) regulating expression of the exogenous gene in the test animals to allow production of the biomolecule; and
- c) monitoring the test animals for growth of the cells wherein observing fewer of the cells or a slower growth rate of the cells in the test animals compared to the number of the cells or growth rate of the cells in the control animals indicates that the biomolecule inhibits growth of cells *in vivo*.

68. (Previously presented) The method of claim 67, further comprising the step of first constructing the cell having the exogenous regulable gene encoding the biomolecule.

69. (Currently amended) The method of claim 67, further comprising the steps of first

- i) constructing the cell having the exogenous regulable gene encoding the biomolecule;
- ii) regulating expression of the exogenous regulable gene in a culture of constructed cells, thereby producing the biomolecule in the constructed cells; and

- iii) monitoring growth of the constructed cells in culture, relative to growth of control cells, whereby, if growth is decreased in the constructed cell, compared to growth of the control cell, then the biomolecule inhibits growth in culture.

70. (Previously presented) The method of claim 67, wherein the protein target component comprises a complex comprising more than one gene product.

71. (Currently amended) The method of claim 67, wherein the protein target component comprises a single gene product.

72. (Previously presented) The method of claim 67, wherein the protein target component comprises an enzyme.

73. (Previously presented) The method of claim 67, wherein the biomolecule is a polypeptide or a peptide.

74. (Previously presented) The method of claim 67, wherein the biomolecule is a fusion protein.

75. (Previously presented) The method of claim 67, wherein the cell is a mammalian cell.

76. (Previously presented) The method of claim 67, wherein the cell is a pathogen cell.

77. (Currently amended) The method of claim 68, wherein the protein target

component comprises a single gene product, a complex comprising more than one gene product, or an enzyme.

78. (Previously presented) The method of claim 77, wherein the protein target component comprises an enzyme.

79. (Previously presented) The method of claim 78, wherein the biomolecule is a polypeptide.

80. (Previously presented) The method of claim 78, wherein the biomolecule is a peptide.

81. (Previously presented) The method of claim 78, wherein the biomolecule is a fusion protein.

82. (Previously presented) The method of claim 77, wherein the cell is a mammalian cell.

83. (Previously presented) The method of claim 77, wherein the cell is a pathogen cell.

84. (Currently amended) A method for determining whether a biomolecule inhibits infection by a pathogen cell in vivo, comprising

- a) introducing a pathogen cell having an exogenous regulable gene encoding a biomolecule into one or more test animals and into one or more control animals, wherein the biomolecule binds a protein target component of the pathogen cell;

- b) regulating expression of the exogenous gene in the test animals to allow production of the biomolecule; and
- c) monitoring the test animals for signs of infection wherein observing fewer or less severe signs of infection in the test animal compared to signs of infection in the control animal indicates that the biomolecule inhibits infection by the pathogen in vivo.

85. (Previously presented) The method of claim 84, further comprising the step of first constructing the pathogen cell having the exogenous regulable gene encoding the biomolecule.

86. (Currently amended) The method of claim 84, further comprising the steps of first

- i) constructing the pathogen cell having the exogenous regulable gene encoding the biomolecule;
- ii) regulating expression of the exogenous regulable gene in a culture of constructed pathogen cells, thereby producing the biomolecule in the constructed pathogen cells; and
- iii) monitoring growth of the constructed pathogen cells in culture, relative to growth of control cells, whereby, if growth is decreased in the constructed pathogen cell, compared to growth of the control cell, then the biomolecule inhibits growth in culture.

87. (Previously presented) The method of claim 84, wherein the protein target component comprises a complex comprising more than one gene product.

88. (Currently amended) The method of claim 84, wherein the protein target component comprises a single gene product.
89. (Previously presented) The method of claim 84, wherein the protein target component comprises an enzyme.
90. (Previously presented) The method of claim 84, wherein the biomolecule is a peptide or a polypeptide.
91. (Previously presented) The method of claim 84, wherein the biomolecule is a fusion protein.
92. (Currently amended) The method of claim 85, wherein the protein target component comprises a single gene product, a complex comprising more than one gene product, or an enzyme.
93. (Previously presented) The method of claim 92, wherein the protein target component comprises an enzyme.
94. (Previously presented) The method of claim 93, wherein the biomolecule is a polypeptide.
95. (Previously presented) The method of claim 93, wherein the biomolecule is a peptide.
96. (Previously presented) The method of claim 93, wherein the biomolecule is a

fusion protein.

97. (Currently amended) A method of determining whether a peptide or a polypeptide inhibits growth of cells *in vivo*, comprising:

- a) introducing a cell having an exogenous regulable gene encoding a peptide or a polypeptide into one or more test animals and into one or more control animals,
- b) regulating expression of the exogenous gene in the test animals to allow production of the peptide or the polypeptide; and
- c) monitoring the test animals for growth of the cells wherein observing fewer of the cells or a slower growth rate of the cells in the test animals compared to the number of the cells or growth rate of the cells in the control animals indicates that the biomolecule inhibits growth of cells *in vivo*.

98. (Previously presented) The method of claim 97, further comprising the step of first constructing the cell having an exogenous regulable gene encoding the peptide or the polypeptide.

99. (Currently amended) The method of claim 97, further comprising the steps of first

- i) constructing the cell having the exogenous regulable gene encoding the peptide or polypeptide;
- ii) regulating expression of the exogenous regulable gene in a culture of constructed cells, thereby producing the peptide or polypeptide in the constructed cells; and
- iii) monitoring growth of the constructed cells in culture, relative to growth of

control cells, whereby, if growth is decreased in the constructed cell, compared to growth of the control cell, then the peptide or polypeptide inhibits growth in culture.

100. (Previously presented) The method of claim 97, wherein the peptide or the polypeptide binds a target component of the cell.

101. (Previously presented) The method of claim 97, wherein the polypeptide is a fusion protein.

102. (Previously presented) The method of claim 100, wherein the target component comprises a complex comprising more than one gene product.

103. (Previously presented) The method of claim 100, wherein the target component comprises a gene product.

104. (Previously presented) The method of claim 100, wherein the target component comprises an enzyme.

105. (Previously presented) The method of claim 97, wherein the cell is a mammalian cell.

106. (Previously presented) The method of claim 97, wherein the cell is a pathogen cell.

107. (Previously presented) The method of claim 98, wherein the peptide or the polypeptide binds a target component of the cell.

108. (Previously presented) The method of claim 107, wherein the target component comprises a gene product, a complex comprising more than one gene product, or an enzyme.

109. (Previously presented) The method of claim 108, wherein the cell is a mammalian cell.

110. (Previously presented) The method of claim 108, wherein the cell is a pathogen cell.

111. (Currently amended) A method for determining whether a peptide or a polypeptide inhibits infection by a pathogen cell *in vivo*, comprising:

- a) introducing a pathogen cell having an exogenous regulable gene encoding a peptide or a polypeptide into one or more test animals and into one or more control animals;
- b) regulating expression of the exogenous gene in the test animals to allow production of the peptide or the polypeptide; and
- c) monitoring said test and control animals for signs of infection; whereby observing fewer or less severe signs of infection in said test animal compared to signs of infection in the control animal indicates that the peptide or polypeptide inhibits infection by the pathogen cell *in vivo*.

112. (Previously presented) The method of claim 111, further comprising the step of first constructing the pathogen cell having an exogenous regulable gene encoding the peptide or the polypeptide.

113. (Currently amended) The method of claim 111, further comprising the steps of first

- i) constructing the pathogen cell having the exogenous regulable gene encoding the peptide or polypeptide;
- ii) regulating expression of the exogenous regulable gene in a culture of constructed pathogen cells, thereby producing the peptide or polypeptide in the constructed pathogen cells; and
- iii) monitoring growth of the constructed pathogen cells in culture, relative to growth of control cells, whereby, if growth is decreased in the constructed pathogen cell, compared to growth of the control cell, then the peptide or polypeptide inhibits growth in culture.

114. (Previously presented) The method of claim 111, wherein the peptide or the polypeptide binds a target component of the cell.

115. (Previously presented) The method of claim 111, wherein the peptide or polypeptide is a fusion protein.

116. (Previously presented) The method of claim 114, wherein the target component comprises a complex comprising more than one gene product.

117. (Previously presented) The method of claim 114, wherein the target component comprises a gene product.

118. (Previously presented) The method of claim 114, wherein the target component

comprises an enzyme.

119. (Currently amended) A method for identifying a compound which is a candidate for producing a phenotypic effect in a cell *in vivo*, said method comprising the steps of:

- a) introducing a cell having an exogenous regulable gene encoding a biomolecule into one or more animals;
- b) regulating expression of the exogenous gene in the animals to allow production of the biomolecule;
- c) monitoring said cell in the animal for the phenotypic effect; and
- d) identifying, if the biomolecule caused the phenotypic effect, one or more compounds that competitively bind to a target cell component to which the biomolecule binds, whereby if the compound competitively binds to the target cell component, then the compound is a candidate for producing the phenotypic effect *in vivo*.

120. (Previously presented) The method of claim 119, further comprising the step of first constructing the cell having the exogenous regulable gene encoding the biomolecule.

121. (Currently amended) The method of claim 119, further comprising the steps of first

- i) constructing the cell having the exogenous regulable gene encoding the biomolecule;
- ii) regulating expression of the exogenous regulable gene in a culture of constructed cells, thereby producing the biomolecule in the constructed cells; and
- ii.) monitoring growth of the constructed cells in culture, relative to growth of

control cells, whereby, if growth is decreased in the constructed cell, compared to growth of the control cell, then the biomolecule inhibits growth in culture

122. (Previously presented) The method of claim 119, wherein the biomolecule is a polypeptide or a peptide.

123. (Previously presented) The method of claim of claim 119, wherein the biomolecule is a fusion protein.

124. (Previously presented) The method of claim 119, wherein the cell is a mammalian cell.

125. (Previously presented) The method of claim 119, wherein the cell is a pathogen cell.

126. (Previously presented) The method of claim 119 wherein the phenotypic effect is growth inhibition.

127. (Previously presented) The method of claim 120 wherein the phenotypic effect is growth inhibition.

128. (Previously presented) The method of claim 127 wherein the biomolecule is a peptide or polypeptide.

129. (Previously presented) The method of claim 128, wherein the biomolecule is a

fusion protein.

130. (Previously presented) The method of claim 129 wherein the cell is a mammalian cell.

131. (Previously presented) The method of claim 129 wherein the cell is a pathogen cell.